

Docket No. 2003-003R1 Application Serial No. 10/790,956 Inventor: Carlson et al. Filed: March 1, 2004
Title: Evaluating Effects Of Exposure Conditions On Drug Samples

Over Time

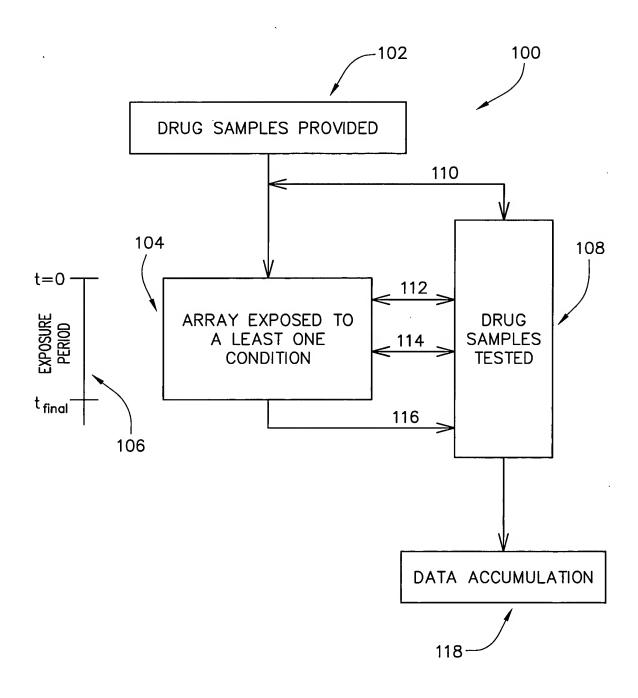
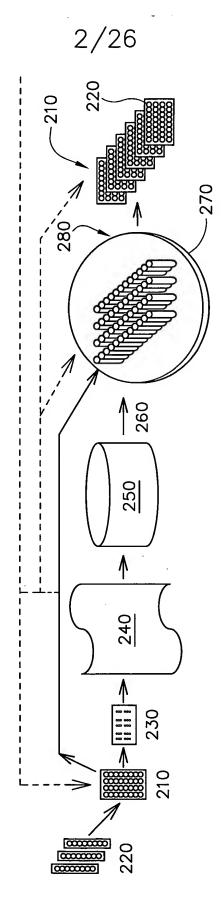


FIGURE 1

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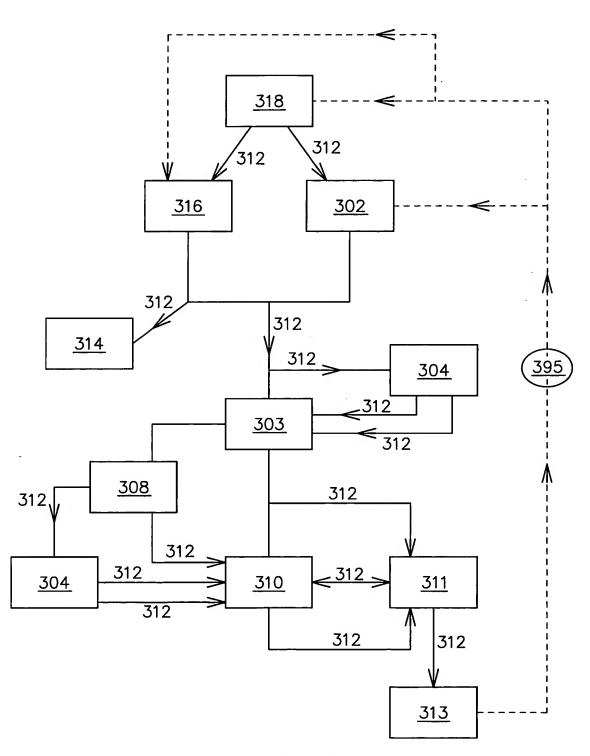


FIGURE 3

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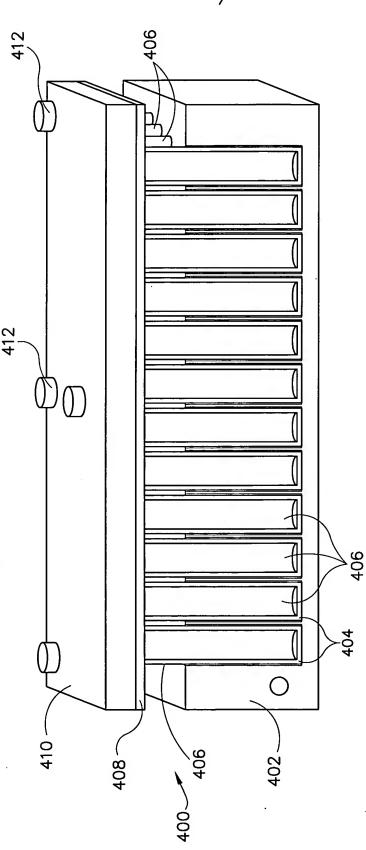
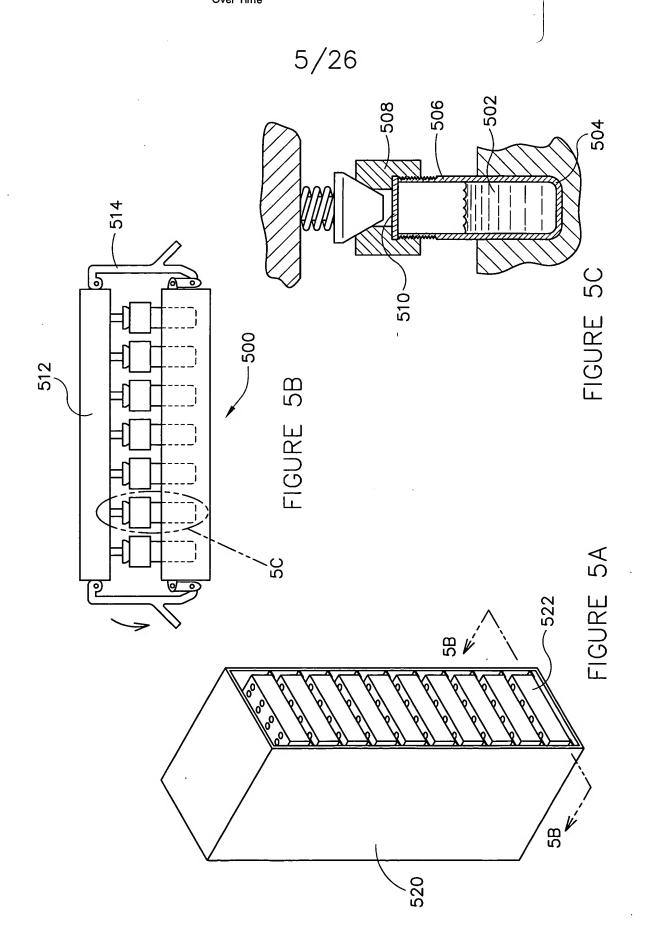


FIGURE 4

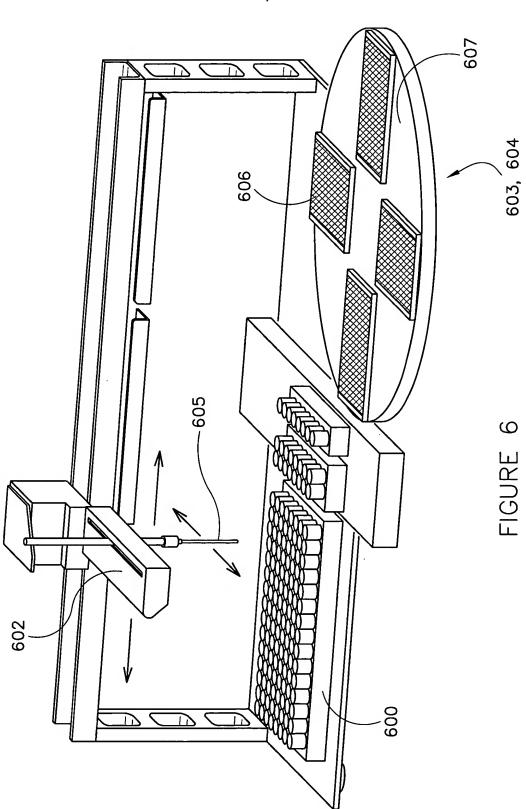
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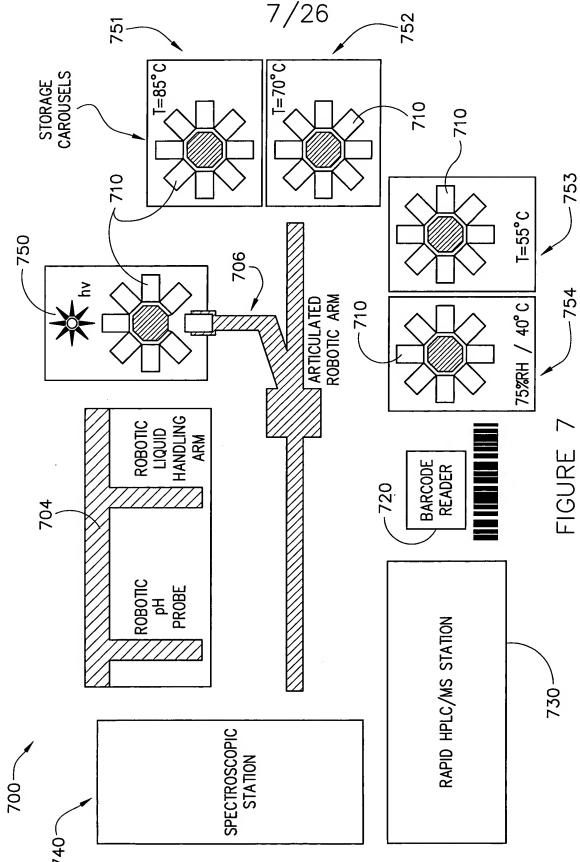


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		8	/2	26		10.0 mg/mL					
0		0.4 mg/mL	2.0 mg/mL	10.0 mg/mL	50.0 mg/mL	ETHANOL (20wt%)	PROPYLENE GLYCOL (20wt%)	AIBN (1eq)	HOOH (1eq)		
12	12					:					
11	11										
10 11 12	9   10   11   12		= .								
6	6		-	•							
8	8										
7	рн 7		i								
9	9										
5	5										
4	4										
3	3										
2	2										
<del></del>	UNCONTROLLED	V	В	O	D	E	F	g	H		

AQUEOUS SOLUTIONS WITH A TOTAL VOLUME OF 800 uL/well FIGURE 8A

EXCIPIENT COMPATIBILITY - SOLIDS FORMULATIONS

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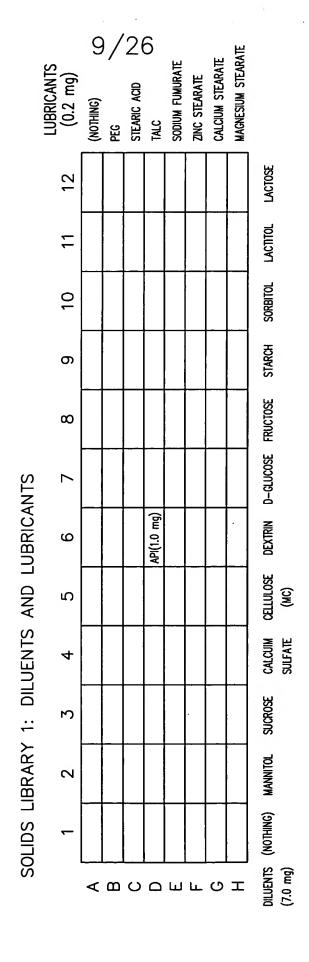


FIGURE 8B

EXCIPIENT COMPATIBILITY - SOLIDS FORMULATIONS

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> DESSICANT COLORANT

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		(SNIHTON)			IYON OXIDE				]		
RSS	GLIDANT	(NOTHING)	SILICON DIOXIDE	CALCIUM SILICATE	TALC	(NOTHING)	SILICON DIOXIDE	CALCIUM SILICATE	TALC		
RICANT WITH BINDERS, GLIDANTS, COLORANTS, ACIDIFIERS, ALKYLIZERSS	12									MAGNESIUM OXIDE	
IERS, A	Ξ									(NOTHING) CITRIC ACID	POVIDONE
ACIDIF	10									(NOTHING)	
RANTS,	თ									MAGNESIUM Oxide	CELLULOSE
s, colc	ω	RANT	ICANT	ANT						(NOTHING) CATRIC ACID MAGNESIUM OXIDE	HYDROXYPROPYL METHYLCELLULOSE
LIDANT	7	1.0 mg COLORANT	1.0 mg COLORANT 10 mg DESSICANT	10 mg DESSICAN						(NOTHING)	
ERS, G	9									MAGNESIUM OXIDE	SE, SODIUM
TH BIN	Ω	ER.	er Uster							(NOTHING) CITRIC ACID MACNESIUM OXIDE	CARBOXYMETHYLCELLULOSE, SODIUM
ANT W	4	5.0 mg BINDER	1 eq Ph Adjuster							(NOTHING)	CARBOXYM
LUBRIC	ы									MAGNESIUM OXIDE	
ARY 2: NT AND	7		D DILUENT	D DILUENT						(NOTHING) CITRIC ACID MAGNES	(NOTHING)
SOLIDS LIBRARY 2: FIXED DILUENT AND LUBI	<b>-</b>	1.0 mgdc	7.0 mg fixed diluent	2.0 mg fixed diluent						(NOTHING)	
SOLIC		∢	æ	O	۵	ш	L.	ပ	I	ЬH	BINDER

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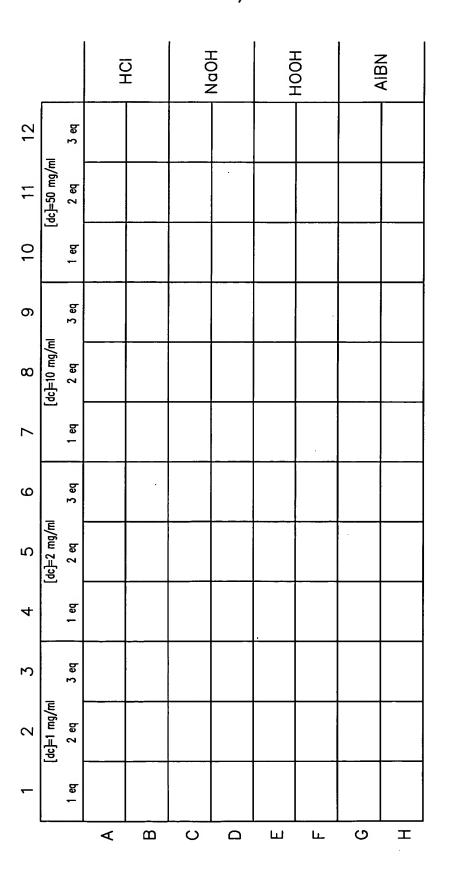


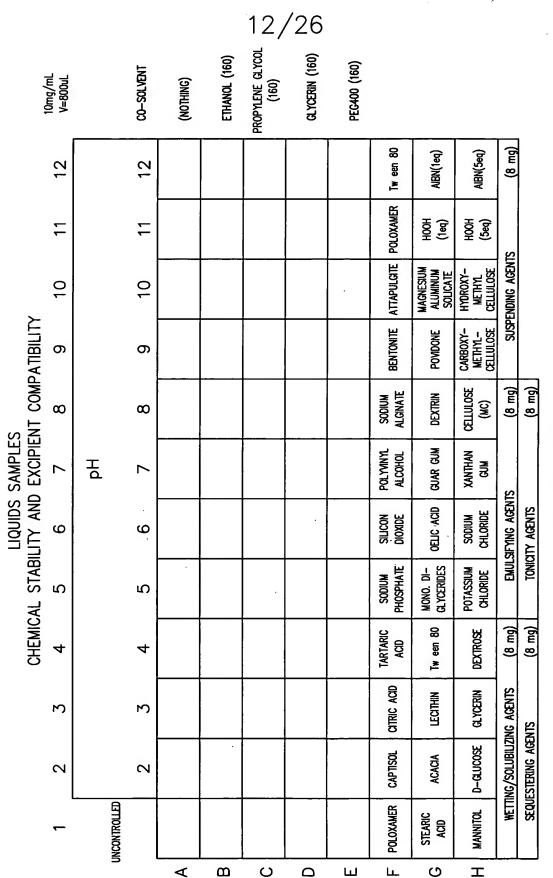
FIGURE 8D

TOTAL VOLUME = 800uL/well dc = DRUG CANDIDATE

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8 E FIGURE

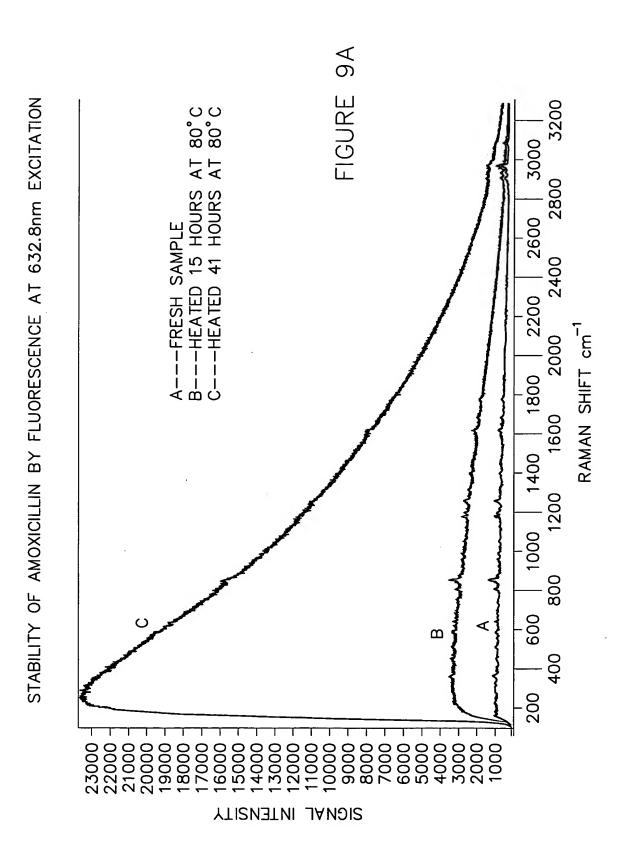
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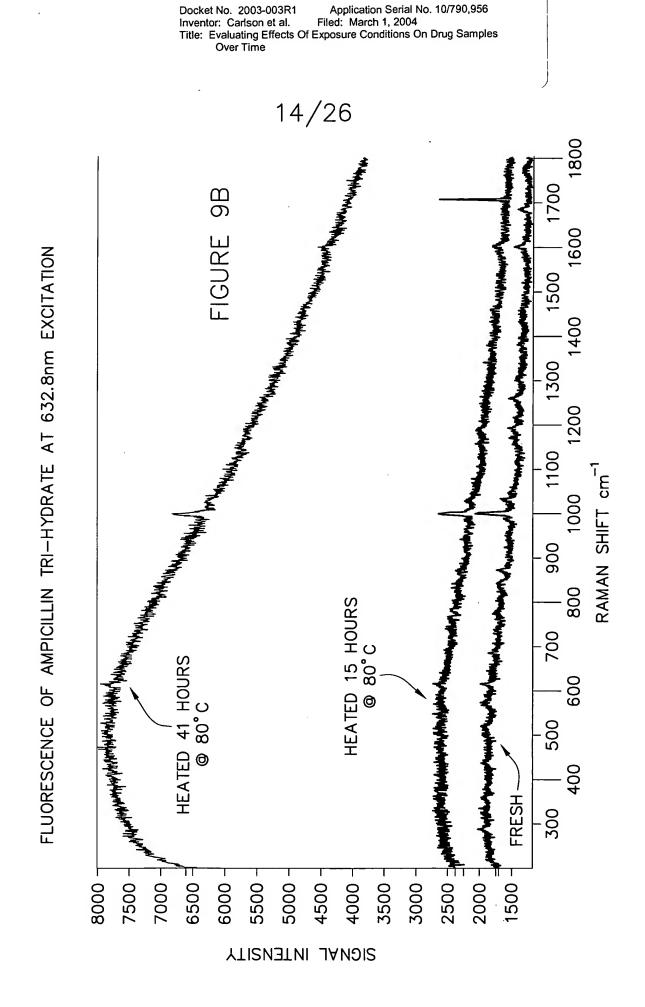
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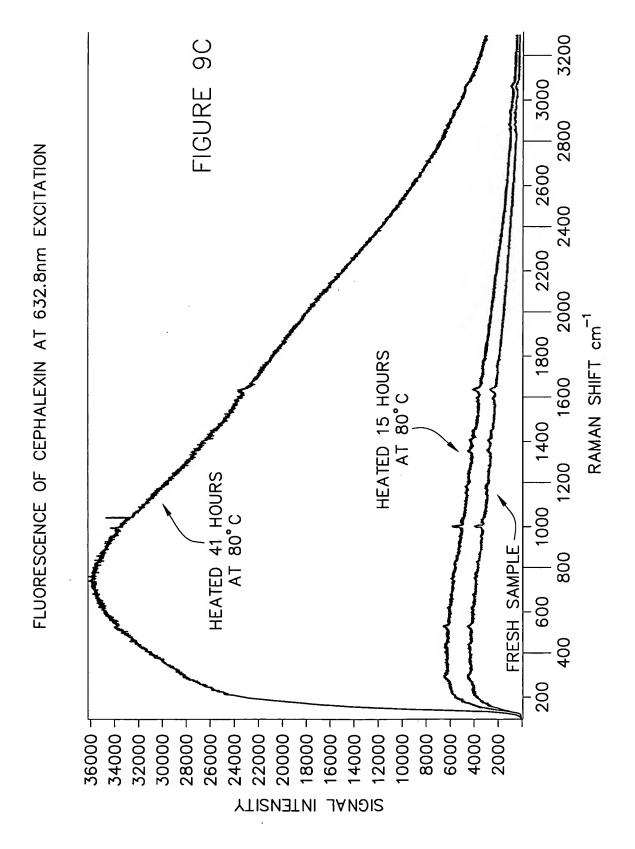
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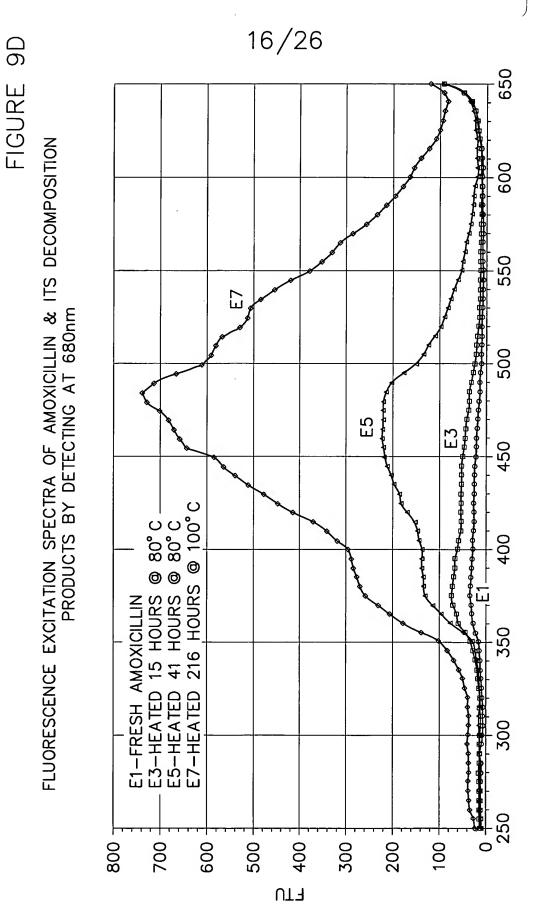
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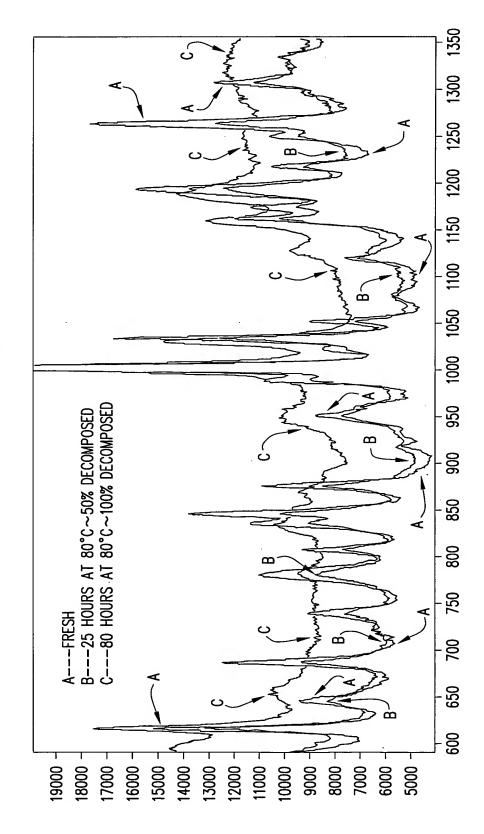


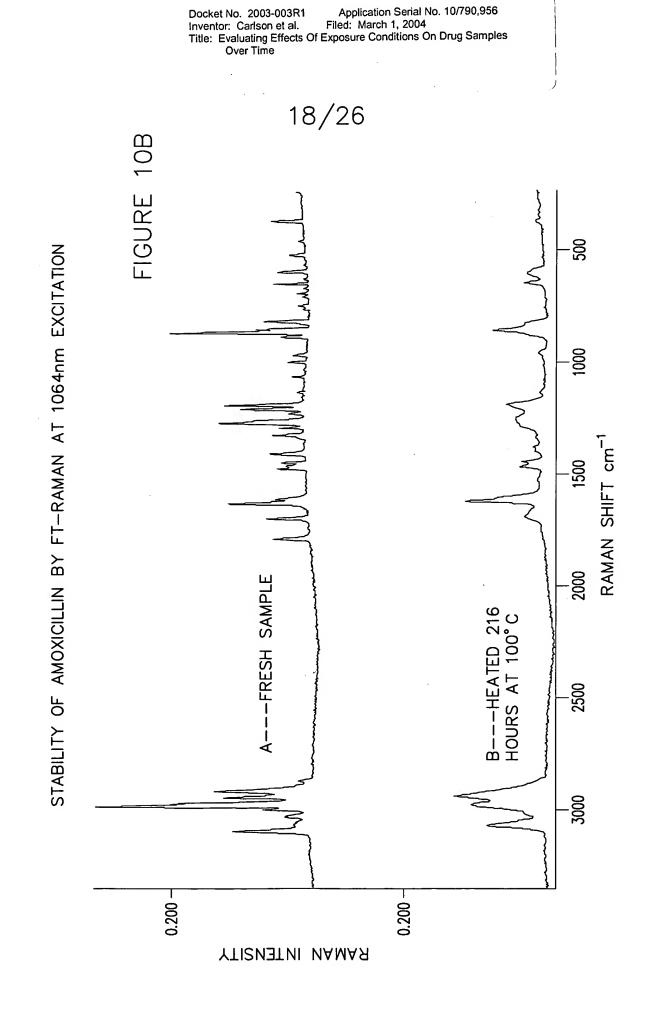
Ex WAVELENGTH IN nm (Em: 680nm)

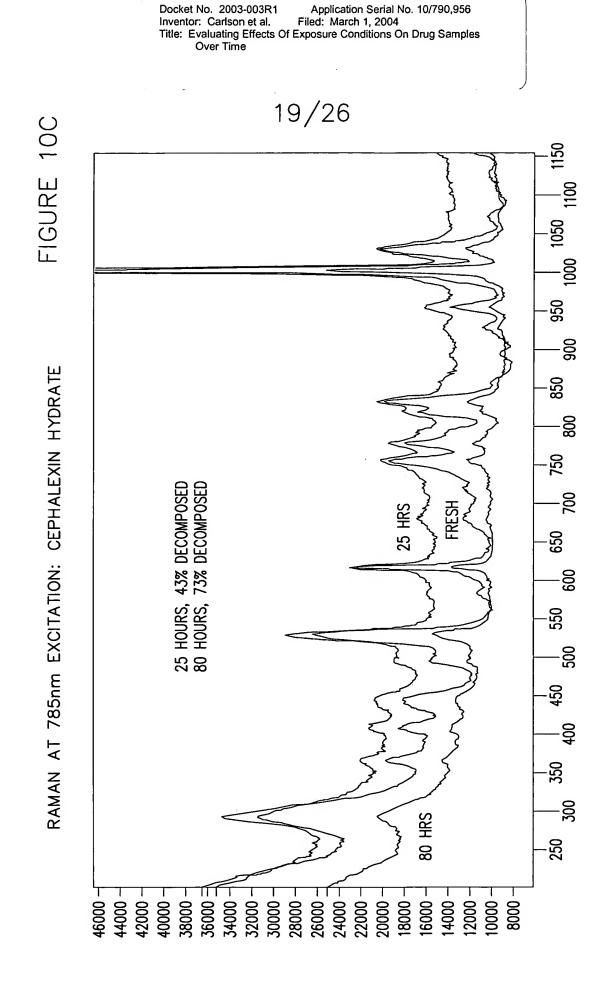
FIGURE 10A

RAMAN AT 785nm EXCITATION: AMPICILLIN TRIHYDRATE

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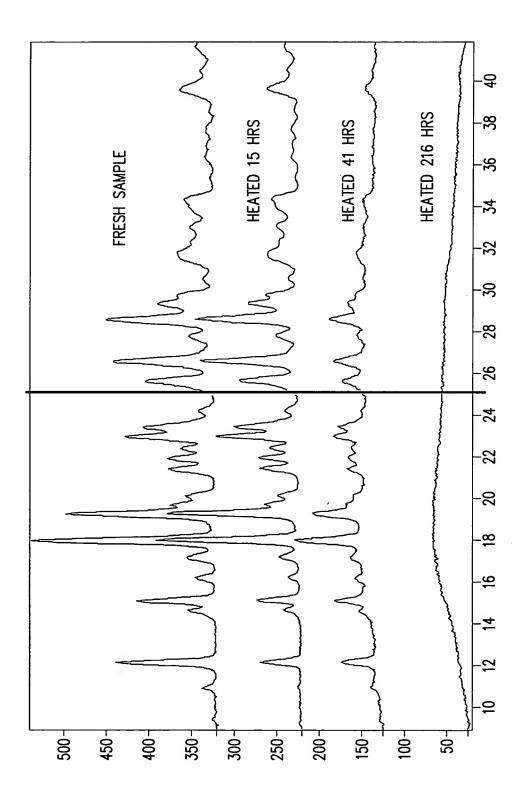


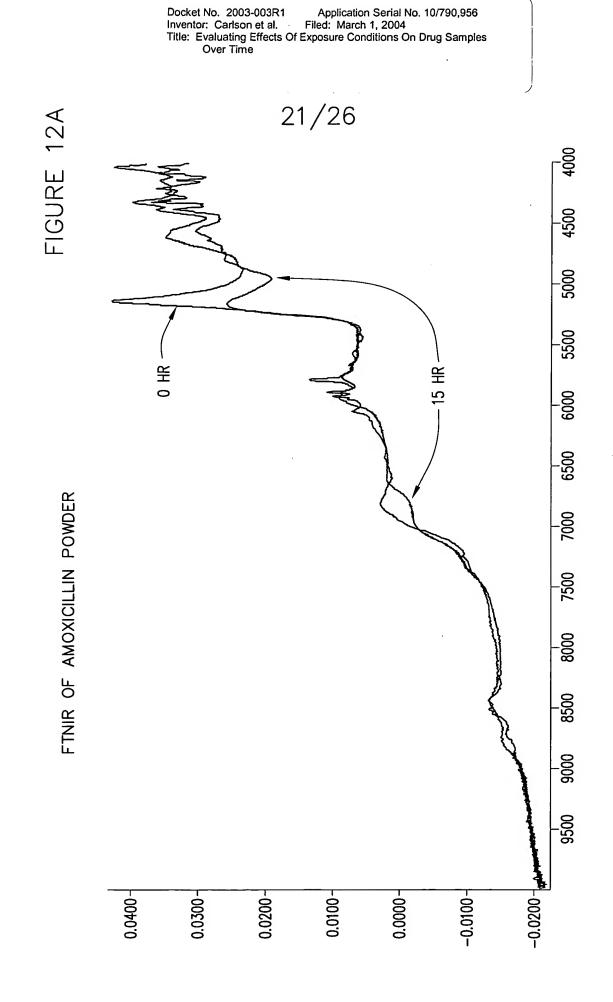




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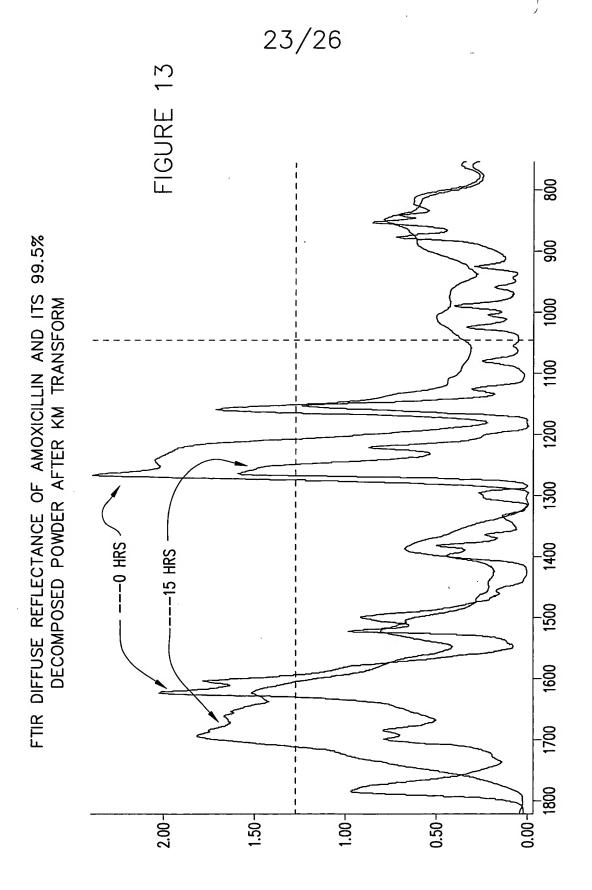


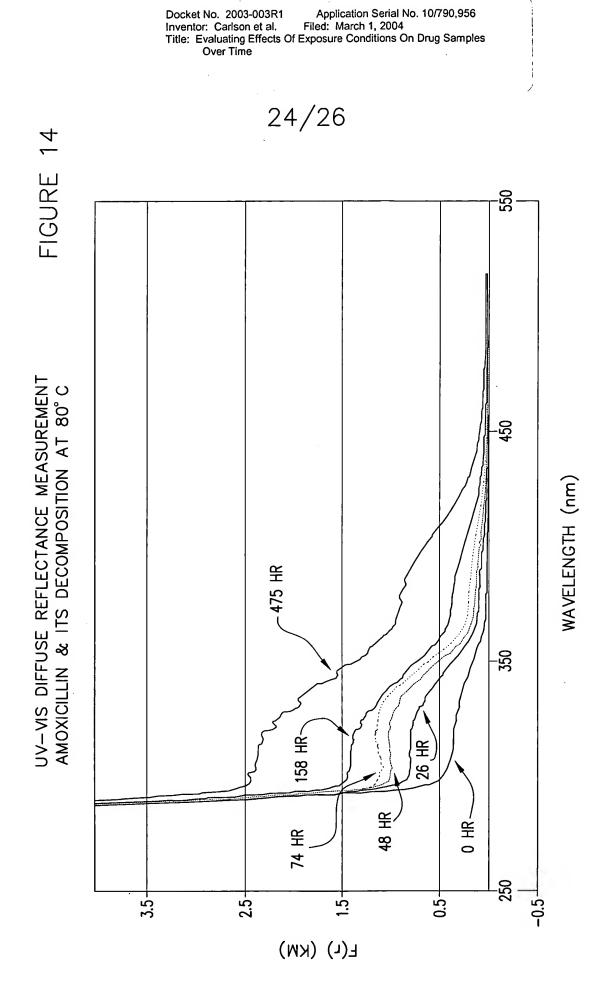


22/26 FIGURE 12B FTNIR OF CEPHALEXIN POWDER IN 8-mL VIALS AFTER 0, 25, 80 HRS @ 80°C 5000 5200 0 HR ----25 HR ---80 HR 0009 10.00 7.50-2.50-0.00 5.00-

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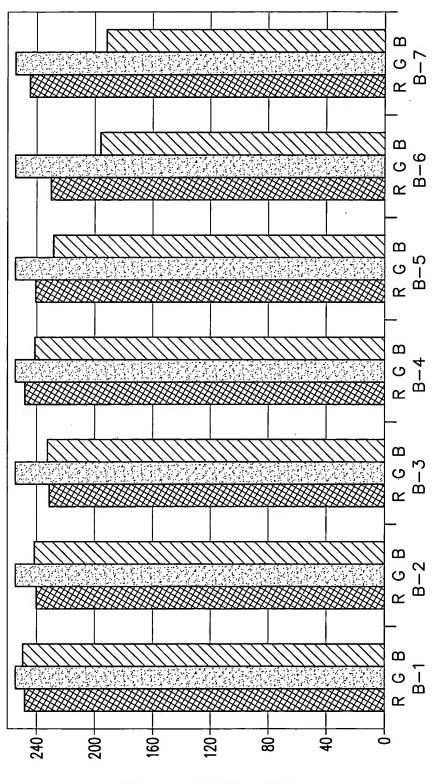
COLORS OF AMOXICILLIN BATCH-1 SAMPLES

12.00 **第四个字**  $\propto$  $\mathbf{\omega}$ A A G B 1.00 RG A-G B A 120.00  $\simeq$  $\mathbf{m}$ ග ď  $\mathbf{\omega}$ ပ \$24.49P\$\$ Ĭ V  $\propto$ മ A-4 200 ပ  $\simeq$ G B 100  $\propto$ മ A  $\alpha$ A-1 R G 40--0 200-င္ထ <del>.</del>60 COLOR INTENSITY

SAMPLE NUMBER

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% OF COLOR INTENSITY

15B

COLOR OF AMOXICILLIN BATCH-2 SAMPLES